PRODUCT: 21 gross of *prophylactics* at Los Angeles, Calif. Examination of samples showed that 2.8 percent were defective in that they contained holes.

LABEL, IN PART: "Three Roger (O. K.)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label designation "Prophylactic" was false and misleading as applied to an article containing holes.

DISPOSITION: July 24, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

3518. Misbranding of Sleepene tablets. U. S. v. 32 Bottles * * *. (F. D. C. No. 31213. Sample No. 23532–L.)

LIBEL FILED: June 22, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about February 1, 1951, by the Sleepene Co., Inc., from New York, N. Y.

PRODUCT: 32 125-tablet bottles of *Sleepene* at Hackensack, N. J.

LABEL, IN PART: "Tablets Sleepene * * * Active Ingredients Aluminum Hydroxide, Acetylsalicylic Acid (Aspirin), Magnesium Trisilicate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Sleepene Helps You Sleep if insomnia is due to simple irritability, nervousness or tension" was false and misleading since the article would not help one sleep.

DISPOSITION: August 14, 1951. Default decree of condemnation and destruction.

3519. Misbranding of Dr. Pierre's Boro-Pheno-Form suppositories. U. S. v. 24 Boxes, etc. (F. D. C. No. 29978. Sample No. 84801–K.)

LIBEL FILED: November 3, 1950, Southern District of Ohio.

ALLEGED SHIPMENT: On or about September 29, 1950, by the Dr. Pierre Chemical Co., from Chicago, Ill.

PRODUCT: 24 boxes, each containing 12 packages, of *Dr. Pierre's Boro-Pheno-Form suppositories* at Dayton, Ohio, together with a number of accompanying leaflets entitled "Feminine Hygiene The Boro-Pheno-Form Way."

Analysis showed that the product contained approximately 14.5 percent boric acid and 3.5 percent quinine sulfate, together with salicylic acid, zinc phenolsulfonate, menthenamine, red cinchona bark, zinc sulfate, cocoa butter, and paraffin.

LABEL, IN PART: (Package) "Dr. Pierre's Boro-Pheno-Form 12 Suppositories."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing on the package label and in the leaflets were false and misleading since the statements represented and suggested that the article was effective for promoting personal cleanliness and feminine hygiene, whereas the article was not effective for such purposes.

DISPOSITION: August 3, 1951. Default decree of destruction.

3520. Misbranding of Buno Medicine. U. S. v. 80 Bottles * * *. (F. D. C. No. 31030. Sample No. 2890–L.)

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*See also Nos. 3503, 3505, 3508, 3510–3515, 3517.

LIBEL FILED: May 4, 1951, Southern District of West Viriginia.

ALLEGED SHIPMENT: On or about March 27, 1951, by Buno Co., Inc., from Philadelphia, Pa.

PRODUCT: 34 1-pint bottles and 46 8-ounce bottles of *Buno Medicine* at Charleston, W. Va.

LABEL, IN PART: "Buno Double Strength Medicine Resorcinol Cantharides Lycopodium Alcohol 38%."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "In Treatment of Stubborn or Severe Cases of Dandruff, Alopecia, Psoriasis, Eczema and Various other Skin and Scalp Disorders or Diseases" was false and misleading since the article was not effective in the treatment of such conditions.

DISPOSITION: July 2, 1951. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3501 TO 3520

PRODUCTS

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3521–3540

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 7, 1952.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 3521, 3523, 3524, 3532; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3523–3525, 3532; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3523, 3524; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 3535; cosmetic, actionable under the drug provisions of the Act, see No. 3532 (Regene No. 29).

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3521. Misbranding of Oxylin antiseptic tablets and Nef-Tex tablets. U. S. v. Louis E. Evons (Drexel Laboratories), and Meredith Evons. Pleas of guilty. Fine of $350 against each defendant. (F. D. C. No. 30563. Sample Nos. 48797–K, 67509–K, 73621–K, 73946–K, 73947–K, 81007–K, 81107–K.)

INFORMATION FILED: April 17, 1951, Eastern District of Pennsylvania, against Louis E. Evons, trading as Drexel Laboratories, Drexel Hill, Pa., and Meredith Evons, manager.

ALLEGED VIOLATION: On or about April 29 and December 13, 1949, and February 7 and 14, March 3, and May 10, 1950, the defendants caused quantities of *Oxylin antiseptic tablets* and *Nef-Tex tablets* to be introduced and delivered for introduction into interstate commerce, at Upper Darby and Drexel Hill, Pa., for delivery to Newton, East Orange, Flemington, and Newark, N. J., Albany, N. Y., and Baltimore, Md.

Between February 12 and May 8, 1950, while a number of *Oxylin antiseptic tablets* were being held for sale at the Drexel Laboratories after shipment in interstate commerce from Camden, N. J., the defendants caused a number of the tablets to be repacked and relabeled, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: *Oxylin antiseptic tablets.* Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented and suggested that the article was an intestinal and urinary antiseptic; that it would be efficacious to arrest fermentation and allay irritation; and that it would be efficacious in the treatment of hyperacidity, intestinal toxemia, diarrhea, amebic and bacillary dysentery, bed wetting, gonorrhea, nephritis, pyelitis, cystitis, pyuria, intestinal grippe, influenza, and the common cold. The article was not an intestinal and urinary antiseptic, and it would not be efficacious for the purposes represented. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients; and it failed to bear a label containing the common or usual name of each of the active ingredients since it contained boric acid as one of its active ingredients, and the label of the article failed to declare the presence of boric acid. Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Dosage: Adults, 3 tablets swallowed with water on an empty stomach, 3 or 4 times daily. In acute or stubborn cases increase dosage to three tablets every two hours. Children, one tablet, four times daily," since such use of the article may result in boric acid poisoning.

Nef-Tex tablets. Misbranding, Section 502 (a), certain statements in the labeling of the article, which included an accompanying brochure headed "Nef-Tex Tablets," were false and misleading. The statements represented and suggested that the article would be efficacious to inhibit bacteria, arrest fermentation, remove the cause of intestinal and urinary irritations, and give quick relief from grippe and the common cold. The article would not be efficacious for the purposes represented.

DISPOSITION: September 11, 1951. Pleas of guilty having been entered, the court imposed a fine of $350 against each defendant.